

Remarks

Claims 1-18 are in the case. Each of the claims stands rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 6,468,284 to Wallace. The rejection is respectfully traversed.

To begin with, each of Applicant's independent claims 1, 5 and 17 recite patentably distinct elements that are not taught or suggested by Wallace, and which serve to plainly distinguish the parties' respective disclosures.

For example, independent claims 1, 5 and 17 recite at least the following patentably distinct claim elements:

Claim 1: "means for measuring electronically the magnitude of the extraction force applied to the fetal head during a vacuum extraction";

Claim 5: "means for measuring the extraction forces exerted on the fetal head, said means contained in said handle grip"; and

Claim 17: "means for measuring the extraction forces on the fetal head".

As seen, the common term between and amongst these clauses is a "means for measuring the extraction forces" applied to the head of the baby while extracting the child during delivery.

In contrast, Applicant submits that Wallace does *not* measure extraction forces applied to the baby's head by the vacuum cup, but instead measures (i) the magnitude of the vacuum pressure against the fetal head, (ii) the duration of a specific application of the vacuum device (or the cumulative duration based upon multiple applications), and (iii) the number of times traction force is applied to the cup (though *not* the magnitude of the extraction forces), in order to "ameliorate or avoid potentially undesirable effects of the vacuum to the fetal head." (See Wallace at col. 2, lines 13-15; see also the Wallace "vacuum reservoir" represented by drawing

element 26 and attendant text within the description, for example, at col. 4, lines 41-2 and col. 4, lines 56-66).

In further support of this argument, Applicant points to the Wallace disclosure of a strain gauge at col. 8, lines 35-6, which admittedly does suggest the use of such a device during a fetal delivery, but only to determine *if and when* a traction force is being applied. The Wallace strain gauge does *not*, however, measure the magnitude of extraction forces exerted on the fetal head, essentially because Wallace is primarily concerned with determining the number of times traction is applied during the delivery (and also the length of time a cup is applied to the fetus, in both individual and cumulative applications), rather than measuring the magnitude of applied extraction forces as claimed herein.

In short, Applicant's claimed invention includes a means for electronically measuring the *magnitude of extraction forces* applied to a vacuum cup (typically in lbs.) in order to prevent the well-documented fetal injuries secondary to sudden cup detachments during a vacuum-assisted delivery (for a detailed discussion of deleterious cup detachments occurring as a function of inadequate vacuum pressure, extended application of the vacuum cup to a baby's head, and inconsistent application of approximately 600 mmHg of cup pressure "regardless of [the] type of cup," see *Vacca A. Handbook of Vacuum Extraction in Obstetric Practice*, Vacca Research (1999), at pages 19-64).

In contrast, Wallace's device is designed to measure *the magnitude of the vacuum pressure* (in mmHg), the duration of a specific application of the vacuum device (or the cumulative duration based upon multiple applications), and the number of times traction forces are applied to the cup, but *not* the magnitude of applied extraction forces. Applicant submits that Wallace's disclosure, while consistent with prior attempts to limit injury to a child during delivery using

previously known correlative factors, completely fails to teach, suggest or appreciate the measurement of applied extraction forces during the delivery process.

In summary, since the Wallace device measures only the *magnitude of the vacuum pressure* exerted by a vacuum cup against the baby's head rather than the *magnitude of applied extraction forces* as claimed herein, it follows that Wallace is inappropriate for citation against the present claims and should now be removed as a grounds of rejection.

Conclusion

In view of the foregoing, Applicant submits that all outstanding grounds of rejection have been overcome with respect to independent claims 1, 5 and 17, each of which should now be allowed. Since all remaining claims in the case depend either directly or indirectly from allowable claims 1, 5 and 17, it follows that all of the remaining claims are also necessarily allowable under the doctrine of *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and withdrawal of the rejections, and allowance of the amended claims presented above at an early date, are respectfully requested.

Respectfully submitted,

  
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